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09/631,339	08/03/2000	Carl T Wittwer	7475-66667	9681
49437 7590 12/14/2006 BARNES & THORNBURG LLP 11 SOUTH MERIDAN STREET INDIANAPOLIS, IN 46204			EXAMINER BEISNER, WILLIAM H	
			ART UNIT 1744	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/631,339

Applicant(s)

WITTWER ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-12,15,19,20 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,5,9-12,15,19,20 and 23-25 is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

***Conclusion***

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/22/2006 has been entered.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143) taken further in view of Gerarde (US 3,518,804) and Hawes (US 3,556,659).

The reference of von Behrens discloses a container (12) for holding a fluidic biological sample that includes a receiving portion (12a) and a reaction portion (12b). A liquid sample positioned within the receiving portion (12a) is capable of flowing into reaction portion (12b). As shown in Figure 1, the receiving portion (12a) has a volume greater than the reaction portion (12b). The reaction volume is not greater than 100 $\mu$ l (See column 4, lines 26-35). With respect to the recited thermal conductivity of the reaction portion, the reference of von Behrens discloses that the reaction portion (12b) is made of glass (See column 4, line 33) which is a material disclosed by the instant specification as a material with the claimed thermal conductivity (See page 53 of the instant specification). The reference of von Behrens discloses that the end of the reaction portion (12b) can be permanently sealed (See column 5, lines 57-67, and Figure 6). With respect to the claimed "wherein the closed end is formed for optical transmissibility through the closed end", the closed end of the reference of von Behrens as discussed previously is considered to meet this claim limitation since it is made of a transparent glass (See column 5, lines 57-67, Figure 6 and column 4, line 33).

With respect to claim 4, while the reference of vonBehrens discloses that portion (12b) of the inner tube device is a **microhematocrit tube** and can vary in volumetric capacity between 0.5 and 100 cubic millimeters (See column 5, lines 24-36), the reference is silent with respect to the wall thickness of the tube. Instant claims 1, 23 and 24 specify a “thin wall” or “0.1mm” thickness.

The reference of Fite et al. discloses that **microhematocrit tubes** having a wall thickness of 0.1mm is known in the art (See column 11, lines 18-24).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the microhematocrit tube disclosed by the reference of Fite et al. as element (12b) of the reference of von Behrens for the known and expected result of providing an art recognized microhematocrit tube within the system of von Behrens as is required of the device of the primary reference.

The instant claim language employs the transitional language “consisting”. The device of von Behrens discloses the additional structure (11). However, this structure is only required when supporting the inner tube (12) within a centrifuge device.

As a result, it would have been obvious to one of ordinary skill in the art to provide the inner tube device (12) as a separate structure from the outer tube device for the known and expected result of using off the self-type of outer tubes (11) that would be provided separately from the inner tube device (12) prior to use. As a result, the inner tube structure (12) alone would meet the structure of instant claim 4.

Claim 4 further differs by reciting that the receiver portion includes a plug.

The reference of Gerarde discloses that it is known in the art to seal the receiver portion (12) of the device that is similar in structure to the device of the modified primary reference with a plug (24) (See Figure 3).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide the receiving section (12a) of the modified primary reference with a plug for the known and expected result of sealing the open end of the tube during storage of the device to protect the interior from contamination and/or protect a contained sample from contamination, exposure and/or leakage from the container.

While the reference of von Behrens discloses that the end of the tube may be sealed (See column 5, lines 63-65 and Figure 6), the reference does not disclose that the sealed end is flat or permits light having a wavelength of about 400nm to about 800nm.

The reference of Hawes discloses that it is conventional in the art to seal the end of a capillary tube such that it forms a flat tip (See Figures 2a and 3-5).

In view of this teaching, it would have been obvious to one having ordinary skill in the art at the time the invention was made to seal the end of the capillary using forming a flat tip as suggested by the reference of Hawes for the known and expected result of providing an alternative means recognized in the art to seal the end of a capillary tube. The method disclosed by the reference of Hawes provides a capillary tube that is capable of being optically interrogated through the end of the capillary tube. Additionally, since glass is employed, it would be capable of passing light in the range of 400nm to 800nm as required of the instant claims.

*Response to Arguments*

6. With respect to the rejection of Claims 1-3, 5, 6, 9, 10, 11, 15, 23 and 24 under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143), this rejection has been withdrawn in view of the amendments to the claims and related comments (See pages 5-14 of the response filed 9/22/2006).

7. With respect to the rejection of Claim 4 under 35 U.S.C. 103(a) as being unpatentable over this rejection has been withdrawn in view of the amendments to the claims and related comments (See pages 14-15 of the response filed 9/22/2006).

Note claim 4 has been amended to include the additional limitation that the closed end of the tube is formed as a flat tip. As a result, new grounds of rejection have been made over the combination of the references of von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143) taken further in view of Gerarde (US 3,518,804) and Hawes (US 3,556,659).

Applicants comment that claim 4 includes all the limitations of claim 1 and therefore is patentable over the combination of von Behrens and Fite et al. for reasons discussed previously.

In response, instant claim 4 does not include all of the limitations of claim 1. Specifically claim 4 does not include any claim limitations with respect to the inner diameter of the tube.

With respect to the combination of the references of von Behrens and Fite et al., the Examiner makes the following comments:

The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the

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**knowledge generally available to one of ordinary skill in the art.** See *In re Fine*, 837

F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941

(Fed. Cir. 1992). In this case, while the reference of von Behrens discloses the combination of the inner tube and outer tube during the centrifugation step, the reference also clearly discloses that the inner tube structure is intended to be removed from the outer tube structure (See column 2, lines 30-39) during the processing steps. Clearly one of ordinary skill in the art would recognize that the inner tube structure can be and is provided as a separate component and at some points during the processing steps is provided as a single component absent the outer tube. Furthermore, one of ordinary skill in the art would clearly recognize that by separately providing the inner tube from the outer tube, the outer tube can be reused.

The motivation for combining the references is provided in the references. First, the reference of von Behrens discloses that a microhematocrit tube is employed in the device (See column 7, lines 44-65). The reference also discloses that the dimensions of the tubes are not critical and can vary. As a result, one of ordinary skill in the art would have recognized and/or been motivated to employ any known microhematocrit tube, such as that disclosed by the reference of Fite et al. The fact that the tube of Fite et al. may be more fragile than other known tubes is immaterial, since the reference of von Behrens recognizes that the tubes are fragile. The reference is completely silent with respect to the use of tube with wall thicknesses greater than others to avoid breakage of the tube. Furthermore, one of ordinary skill in the art would also be motivated to employ the tube of Fite et al. over other tubes for the known and expected advantage of providing a tube that provides rapid heat exchange, especially when performing microhematocrit operations that require temperature control. Finally, the fact that applicant has



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recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

With respect to the combination of the references of von Behrens, Fite et al. and Hawes (US 3,556,659) the Examiner makes the following comments:

First, Applicants argue (See page 15 of the response filed 9/22/06) that there is no motivation to combine the reference of Hawes with the references of von Behrens and Fite et al. because Hawes is drawn to optical interrogation while the references of von Behrens and Fite et al. are silent with respect to optical interrogation.

In response, while the references of von Behrens and Fite et al. may be silent with respect to optical interrogation, the references require a sealed end. The reference of Hawes provides evidence that it is known in the art to seal the end of a capillary tube to have a flat surface. As a result, one of ordinary skill in the art would have recognized that the tube of the modified reference can be sealed with a flat end merely as an alternative means for sealing the end of a capillary tube recognized in the art. The flat surface allows the tube to be optically interrogated while reducing background light.

Finally Applicants argue (See pages 15-16 of the response filed 9/22/06) that the reference of Hawes does not disclose a tube with a flat tip. Applicants stress that the end of the tube of Hawes must be convexed.

In response, while the optical detection system of the reference of Hawes requires that the tube be interfaced with a convex lens, the reference still discloses that a capillary tube can be sealed with a flat tip wherein the flat tip is interfaced with the convex lens during the optical

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interrogation. Clearly one of ordinary skill in the art would recognize that the tube ends can be sealed separately from the lens as disclosed in the reference of Hawes. Additionally, one of ordinary skill in the art would have recognized that when sealing the end of the tube for processing as required of the modified primary reference, the additional convex lens would not be required.

8. With respect to the rejection of Claims 12 and 20 under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143) taken further in view of, this rejection has been withdrawn in view of the amendments to the claims and related comments (See pages 5-14 of the response filed 9/22/2006) since these claims depend from claim 1.

***Allowable Subject Matter***

9. Claims 1-6, 9, 12, 15, 19, 20 and 23-25 are allowed.

10. The following is a statement of reasons for the indication of allowable subject matter:

Claims 1-6, 9, 12, 15, 19, 20 and 23-25 are allowable because while the prior art of record suggests the use of a thin-walled capillary tube in the device of von Behrens as suggested by the reference of Fite et al., none of the prior art references teach or suggest the additional claim feature that the inner diameter of the tube is from about 0.25mm to about 1.0mm which is critical to the instant invention optimization of rapid and uniform temperature modulation of the sample.


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***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB